NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHRISTINE JANKOWSKI *et al.*, Plaintiffs, v. ZYDUS PHARMACEUTICALS USA, INC., *et al.*, Defendants.	Civil Action No. 20-2458 (MAS) (TJB) **MEMORANDUM OPINION**

SHIPP, District Judge

This matter comes before the Court on Defendant Zydus Pharmaceuticals USA, Inc.'s ("Zydus") Motion to Dismiss the Second Amended Complaint. (ECF No. 35.) Plaintiffs[1] opposed (ECF No. 39), and Zydus replied (ECF No. 40). The Court has carefully considered the parties' submissions and decides the matter without oral argument under Local Civil Rule 78.1. For the reasons below, the Court grants Zydus's Motion.

I. BACKGROUND

The parties are familiar with the factual background and the procedural history of this matter, and the Court recites only those facts necessary to resolve the instant Motion. *See Jankowski v. Zydus Pharms. USA, Inc.*, No. 20-2458, 2021 WL 2190913, at *1 (D.N.J. May 28, 2021) ("Mem. Op."), ECF No. 24. This case is one of several in this District and many around the

[1] Plaintiffs are 209 individuals who either ingested Amiodarone or are the family members of individuals who died from or were injured by the drug after being diagnosed with atrial fibrillation. (Second. Am. Compl. 1-135 ("SAC"), ECF No. 27.)

country brought against generic drug manufacturers on behalf of patients prescribed the drug Amiodarone.[2] In the United States, non-party Wyeth obtained approval from the Food and Drug Administration ("FDA") for the use of Amiodarone "as a drug of last resort for patients suffering from documented, recurrent, life-threatening, ventricular fibrillation and ventricular tachycardia when the[] conditions would not respond to other available anti-arrhythmic drugs and therapies." (SAC ¶ 167.) Zydus is a generic manufacturer of Amiodarone. (*Id.* ¶ 177.)

Despite Amiodarone's approval for limited use, Wyeth and several generic manufacturers "aggressively and successfully" marketed Amiodarone for off-label use to treat atrial fibrillation ("a-fib").[3] (*Id.* ¶ 168.) This campaign was so successful that an "entire generation" of physicians prescribed Amiodarone for "off-label" use to treat a-fib. (*Id.*) Although the SAC does not contain allegations that Zydus was one of the generic manufacturers that marketed Amiodarone for off-label use, Plaintiffs allege that Zydus "directly benefitted" from these off-label marketing efforts by "focusing primarily on pricing in their marketing and promotional efforts to increase market share." (*Id.*)

Plaintiffs allege that because of Wyeth and the generic manufacturers' "unlawful promotion" to prescribe Amiodarone for off-label use, they "either directly or indirectly provided the indications and usage information regarding Amiodarone to the distributor of the Physician's

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[2] *E.g.*, *Roncal v. Aurobindo Pharma USA, Inc.*, No. 20-02643, 2022 WL 1237888, at *1 (D.N.J. Apr. 27, 2022); *Medford v. Eon Labs, Inc.*, No. 20-412, 2021 WL 5204035, at *1 (D.N.J. Nov. 9, 2021); *Polt v. Sandoz, Inc.*, 462 F. Supp. 3d 557, 562 (E.D. Pa. 2020), *appeal dismissed*, No. 20-2125, 2021 WL 2328343 (3d Cir. Mar. 16, 2021); *Bean v. Upsher-Smith Pharms., Inc.*, No. 16-01696, 2017 WL 4348330, at *1 (D.S.C. Sept. 29, 2017), *aff'd*, 765 F. App'x 934 (4th Cir. 2019); *Perdue v. Wyeth Pharms., Inc.*, 209 F. Supp. 3d 847, 849 (E.D.N.C. 2016); *Stephens v. Teva Pharms., U.S.A., Inc.*, 70 F. Supp. 3d 1246, 1248 (N.D. Ala. 2014).

[3] In 1985, non-party Wyeth obtained Food and Drug Administration ("FDA") approval to market and sell Amiodarone under the brand name Cordarone.

Desk Reference ("PDR") and the developer of Epocrates[4]", both of which are widely used by physicians to access information about drugs they may prescribe to their patients. (*Id.* ¶ 169.) Specifically, Plaintiffs allege that both the PDR and Epocrates contain misleading information about Amiodarone that deceives physicians into believing Amiodarone:

> (1) is approved for the treatment of [a]-fib when it never was; (2) was not approved solely as a drug of "last resort" for patients with ventric[ular] fibrillation [] facing death; (3) provides benefits to [a]-fib sufferers that outweigh the safety risks; and/or (4) underwent appropriate FDA-approved randomized, clinical trials, which it never did.

(*Id.* ¶ 172.)

Plaintiffs allege that because of the off-label prescription of Amiodarone to treat a-fib, they, their spouses, or the decedents they represent were injured or died as a result. (*Id.* ¶ 179.)

The Court previously dismissed the seven causes of action set out in Plaintiffs' First Amended Complaint for preemption and failure to state a claim. (*See* Mem. Op. 4-14.) Plaintiffs filed a Second Amended Complaint ("SAC") and now re-allege causes of action for failure to warn under the New Jersey Products Liability Act ("NJPLA"), negligence, and wrongful death.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 8(a)(2)[5] requires only 'a short and plain statement of the claim showing that the pleader is entitled to relief,' in order to 'give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.'" *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Conley v. Gibson*, 355 U.S. 41, 47 (1957)). On a motion to dismiss for failure to state a claim, the "defendant bears the burden of showing that no claim has been

[4] Epocrates is a prescription drug reference source available online and via an application usable on smartphones and tablets. (SAC ¶ 170.) Epocrates provides physicians with information about prescription drugs including, but not limited to, uses, warnings, contraindications, and dosage. (*Id.*)

[5] Unless otherwise noted, all references to a "Rule" or "Rules" hereinafter refer to the Federal Rules of Civil Procedure.

presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005) (citing *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991)).

A district court conducts a three-part analysis when considering a motion to dismiss pursuant to Rule 12(b)(6). *See Malleus v. George*, 641 F.3d 560, 563 (3d Cir. 2011). First, the court must "tak[e] note of the elements a plaintiff must plead to state a claim." *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 675 (2009)). Second, the court must "review[] the complaint to strike conclusory allegations." *Id.* The court must accept as true all of the plaintiff's well-pleaded factual allegations and "construe the complaint in the light most favorable to the plaintiff." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citation omitted). In doing so, however, the court is free to ignore legal conclusions or factually unsupported accusations that merely state "the-defendant-unlawfully-harmed-me." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 555). Finally, the court must determine whether "the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Fowler*, 578 F.3d at 211 (quoting *Iqbal*, 556 U.S. at 679). A facially plausible claim "allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 210 (quoting *Iqbal*, 556 U.S. at 678).

III. DISCUSSION

The Court need only address Plaintiffs' first cause of action for failure to warn under the PLA.[6] At bottom, Plaintiffs contend that Zydus failed to communicate FDA warnings concerning

[6] Plaintiffs also allege a cause of action for "negligence – failure to warn" and wrongful death in the alternative to the NJPLA claim. To the extent Plaintiffs argue that the Court should apply the law of their states of residence, they have not identified whether those laws conflict with the forum's law. (*See* Pls.' Opp'n Br. at 8-9.) Given Plaintiffs' failure to identify a conflict, the law of the forum governs. *See, e.g., Gelis v. Bayerische Motoren Werke Aktiengesellschaft*, No. 17-07386, 2018 WL 6804506, at *4 (D.N.J. Oct. 30, 2018) ("[W]here the parties fail to point out or establish any difference in the laws of the various jurisdictions involved in a particular case, it is proper for the court to apply the law of the forum." (quotation marks and citation omitted)). Accordingly, New Jersey law applies.

the dangers associated with Amiodarone to prescribing physicians. (SAC ¶¶ 191-92.) This failure, Plaintiffs allege, was a substantial factor contributing to their injuries. (*Id.* ¶ 193.) Furthermore, Plaintiffs allege that Zydus was or should have been aware that statements made in prescribing reference sources such as the PDR and Epocrates app were misleading and Zydus had a duty to correct those inaccuracies. (*Id.*) As a result of Zydus's inaction, prescribing physicians were not adequately warned that Amiodarone was not safe to prescribe for the treatment of a-fib. (*Id.* ¶ 194.)

In New Jersey, the PLA governs the duty of prescription drug manufacturers to provide warnings about the risks. Thus, the PLA generally subsumes common law product liability claims, making the PLA "the sole basis of relief under New Jersey law available to consumers injured by a defective product."[7] *Repola v. Morbark Indus., Inc.*, 934 F.2d 483, 492 (3d Cir. 1991). The PLA provides the following:

> A manufacturer or seller of a product shall be liable in a product liability action *only if* the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it . . . failed to contain adequate warnings or instructions . . . .

N.J. Stat. Ann. § 2A:58C-2 (emphasis added). Indeed, the statute further clarifies that a manufacturer,

> shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction.

N.J. Stat. Ann. § 2A:58C-4. Further, "[i]f the warning or instruction given in connection with a [drug] has been approved or prescribed by the [FDA] . . ., a rebuttable presumption shall arise that the warning or instruction is adequate." *Id.* "To overcome this presumption, a plaintiff asserting a

[7] To be sure, Plaintiffs here admit as much. (*See* Pls.' Opp'n Br. 6 (naming failure to warn as Plaintiffs' "sole live theory").)

failure to warn claim based on an inadequate label or instructions has stricter pleading requirements. A plaintiff must plead specific facts alleging 'deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects,' or 'manipulation of the post-market regulatory process[.]'" *Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1056 (N.J. 2012), *abrogated on other grounds by McCarrell v. Hoffmann-La Roche, Inc.*, 153 A.3d 207 (N.J. 2017).

In cases involving pharmaceutical manufacturers, like this one, New Jersey applies the learned intermediary doctrine. *See Provenzano v. Integrated Genetics*, 22 F. Supp. 2d 406, 418 (D.N.J. 1998). Under that doctrine, a manufacturer "generally discharges its duty to warn the ultimate users of prescription drugs by supplying physicians with information about the drug's dangerous propensities" and when the manufacturer "simply suppl[ies] the physician[s] with information about product," and does not advertise directly to patients. *Perez v. Wyeth Lab'ys Inc.*, 734 A.2d 1245, 1250 (N.J. 1999); *see also In re Plavix Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. 13-4518, 2017 WL 4838842, at *5 (D.N.J. Oct. 26, 2017).

At the heart of this dispute is what it means to have supplied physicians with information about the drug's dangerous propensities. Under Plaintiffs' reading, Zydus's label was insufficient (even though it was accurate and affixed to bottles sent to pharmacies) because "doctors do not receive labeling attached to prescriptions, and pharmacists generally throw it away." (Pl.'s Opp'n Br. 7.) So, what do Plaintiffs suggest would be enough to discharge Zydus's duty? It is unclear. Plaintiffs suggest that Zydus's duty is to use a method of warning that "gives a reasonable assurance that the information will reach" treating doctors. (*Id.* (citing Restatement (Second) of Torts, § 388).) Plaintiffs do provide examples, however, such as placing the FDA warning in the PDR or taking other "adequate measures to communicate warnings to doctors." (*Id.* at 10.)

Considering New Jersey law, the Court finds that Plaintiffs do not plausibly allege facts to state a claim for relief. As the Third Circuit recently set forth, manufacturers who owe a duty to

warn doctors and physicians generally fulfill that duty when the "warnings provided . . . in connection with the [manufacturer's product] were adequate as a matter of law." *Greisberg v. Bos. Sci. Corp.*, No. 21-2364, 2022 WL 1261318, at *2 (3d Cir. Apr. 28, 2022). In the SAC, Plaintiffs do not challenge that Zydus's warning label was inaccurate. Instead, they claim that the "prescriptions Plaintiffs filled were not accompanied by FDA labeling information." (Pls.' Opp'n Br. 6.) But Plaintiffs' argument ignores that under the learned intermediary doctrine, a patient's treating physician is tasked with providing the patient with a drug's warnings. *Cooper v. Bristol-Myers Squibb Co.*, No. 07-885, 2013 WL 85291, at *4 (D.N.J. Jan. 7, 2013) ("The principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer and the consumer/patient and, therefore, the physician stands in the best position to evaluate a patient's needs and assess the risks and benefits of a particular course of treatment."). Indeed, as the New Jersey Supreme Court examined, unless a drug is directly marketed to consumers (which Plaintiffs do not allege Zydus did), the learned intermediary doctrine relieves a pharmaceutical manufacturer of an independent duty to warn the ultimate user of prescription drugs. *Perez*, 734 A.2d at 1264; *accord Caveny v. CIBA-GEIGY Corp.*, 818 F. Supp. 1404, 1406 (D. Colo. 1992) ("It is the responsibility of the physician as a learned intermediary to assess the risks and benefits of a particular course of treatment.").

Moreover, Plaintiffs' contention that Zydus did not place the FDA warnings in the PDR during the relevant period is irrelevant. (Pls.' Opp'n Br. 19.) Plaintiffs offer no support for the proposition that New Jersey law requires manufacturers to place warnings in the PDR. Finally, Plaintiffs' contention that there is evidence that doctors are not receiving the FDA warnings "because they continue to prescribe Amiodarone" to treat a-fib also fails. (Pls.' Opp'n Br. 20.) This is so because Plaintiffs' belief is simply speculation pled without specificity. *Greisberg*, 2022

WL 1261318, at *1 (plaintiff must plead "specific facts" when alleging deliberate concealment or nondisclosure.)

To bolster their argument, Plaintiffs assert that "many courts have held that a drug manufacturer can be liable if it fails to communicate FDA warnings to doctors." (Pls.' Opp'n Br. 7.) On closer inspection, however, the sole case Plaintiffs cite is an Amiodarone case decided in Plaintiffs' favor in Minnesota state court. *Walsh v. Upsher-Smith Labs., Inc.*, 2021 Minn. Dist. LEXIS 430, at *7 (Oct. 4, 2021). But that case is distinguishable from the one here. There, the court affirmed the trial court's denial of summary judgment, finding a genuine dispute existed concerning the adequacy of the warnings given to physicians. *See Id.* But as the Eighth Circuit observed, Minnesota differed from other jurisdictions in that it had not considered whether "a properly worded package insert is a sufficient warning as a matter of law." *In re Levaquin Prod. Liab. Litig.*, 700 F.3d 1161, 1167 (8th Cir. 2012). By contrast, under New Jersey law, there is a presumption "that a drug warning is adequate if it was approved by the FDA." *Rowe v. Hoffman-La Roche, Inc.*, 189 N.J. 615, 622 (2007).[8] To be sure, the "contention that it is the drug manufacturer's responsibility to warn that the use of its drug should be considered only as a last result for a particular condition is contrary to the law. The physician, not the drug company, has the responsibility to evaluate and compare risks and benefits." *Caveny*, 818 F. Supp. at 1406. Therefore, the Court finds that Plaintiffs fail to assert a plausible claim for failure to warn under the PLA.

[8] To the extent Plaintiffs contend that Zydus's labeling was inaccurate, this Court has already disposed of that allegation. *Jankowski v. Zydus Pharms. USA, Inc.*, No. 20-2458, 2021 WL 2190913, at *6 (D.N.J. May 28, 2021) ("To the extent Plaintiffs' claims are based on the content of the Medication Guide and information about off-label use of Amiodarone in these medical references, the claims are preempted under *Mensing*.").

Furthermore, Plaintiffs' argument that Zydus had a duty to correct information in reference sources such as the PDR and Epocrates also fails. Plaintiffs claim that information contained in the PDR and Epocrates was inaccurate. (SAC ¶ 193.) Plaintiffs also allege that had Zydus not concealed material information, their physicians would not have been misled into prescribing Amiodarone to treat a-fib. *See id.* Plaintiffs further argue that these claims are not preempted because Plaintiffs are not asserting that Zydus should have changed its labeling to ensure proper information was in the reference materials, but instead, are asserting that Zydus had a duty to affirmatively correct information in the reference guides. (Pls.' Opp'n Br. 213-14.)

Regardless, this claim fails because as one court in this district already found in a case brought against another Amiodarone generic manufacturer, "[p]laintiffs' allegations are insufficient to provide a basis for relief." *Roncal v. Aurobindo Pharma USA, Inc.*, No. 20-02643, 2022 WL 1237888, at *9 (D.N.J. Apr. 27, 2022) (Shwartz, J.). Like the plaintiffs in *Roncal*, Plaintiffs here do not:

> (1) "allege what th[e] misleading information was or adduce any examples, beyond vaguely asserting that the effect of the reference materials was to "deceive[] physicians into believing" that Amiodarone safely treated [a-fib]," (2) "tailor their allegations to [Zydus]," (3) explain, if the reference material—e.g., the information in the [PDR] and Epocrates—is "labeling," how [Zydus], "as a generic manufacturer," had "control over this labeling," (4) "explain what [Zydus's] contribution to or authority to correct the reference materials was," or (5) provide a basis to infer from [Zydus] purportedly providing permission to use images of its pills in reference materials that it "controlled the medical content of the reference materials."

Id. (citing *Frei v. Taro Pharms. U.S.A., Inc.*, 844 F. App'x 444, 447 (2d Cir. 2011)).[9] The SAC pleads no facts or plausible legal theory that suggest Zydus was required, or even had authority to correct information in any reference guide. The Court thus finds that this claim also fails.

Finally, Plaintiffs request that this Court grant them leave to amend if it finds that the allegations are insufficiently pled. (Pls.' Opp'n Br. 30.) The district court may deny leave to amend if (a) the moving party's delay in seeking amendment is undue, motivated by bad faith, or prejudicial to the non-moving party or (b) the amendment would be futile. *See Adams v. Gould, Inc.*, 739 F.2d 858, 864 (3d Cir. 1984). After its last Memorandum Opinion, this Court granted Plaintiff an opportunity to amend. (ECF No. 25.) At this juncture, however, the Court is convinced the Plaintiff is proceeding under an insufficient legal theory and therefore any amendment would be futile. *See also Roncal,* No. 20-02643 (D.N.J. Apr. 27, 2022), ECF No. 37 (Shwartz, J.) (dismissing similar claims with prejudice). Accordingly, this case is dismissed with prejudice.

IV. CONCLUSION

For the foregoing reasons, the Court grants Zydus's motion to dismiss. An appropriate order will follow.

/s/ Michael A. Shipp
MICHAEL A. SHIPP
UNITED STATES DISTRICT JUDGE

[9] The Court also dismisses Plaintiffs' wrongful death claim because the Court dismisses all of Plaintiffs' other claims. *Beim v. Hulfish*, 83 A.3d 31, 40 (N.J. 2014); *Giardina v. Bennett*, 545 A.D. 139, 144 (N.J. 1988) ("A wrongful death claim is barred if it "could not have been asserted by a surviving plaintiff on his or her own behalf.").